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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
	3626

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/500,977	SONG, JAMES W.
	Examiner	Art Unit
	Carolyn M Bleck	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 June 2003 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 21,23,24,27,28 and 30-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 21,23,24,27,28 and 30-44 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the RCE filed 27 June 2003. Claims 21, 23, 24, 27, 28, and 30-44 are pending. Claims 22, 25, 26, and 29 are cancelled. Claims 21, 24-33, and 38-40 have been amended. Claims 41-44 are newly added. The Examiner appreciates Applicant's response to the previous Office Action. It is noted that Applicant need only respond to the prior art rejections made in this Office Action (in this case, paper number 9). Applicant is not required to respond to the Examiner's rejections made in the previous two Office Actions (paper numbers 2 and 5).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21, 23-24, 27-28, 30-32, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (6,516,315) in view of Wilkins (6,523,009) and Schoenberg et al. (6,322,502).

(A) As per claims 21, 24, Gupta discloses a method for controlling access to information used in a health care application in a client/ server architecture over a network (Abstract; col. 8 line 60 to col. 9 line 9, col. 12 lines 12-25) comprising:

(a) managing data objects at multiple levels in a database management system, wherein at the finest level, the object may be a single attribute value in a particular instance, wherein a patient folder associated with a specific patient consists of objects having subjects such as patient bio-data, insurance, financial, problems, encounters, and treatment records (col. 3 lines 35-59, col. 8 line 60 to col. 9 line 9, col. 11 line 35 to col. 12 line 25); (“data objects, wherein the object may be a single attribute value in a particular instance” are considered to be a form of Applicant’s “component fields”);

(b) defining a set of access rights initiated when a subject/user ties to perform an operation on a data object by both physicians or a patient’s primary care provider (reads on “health care providers”) and patients (reads on “non health care providers”), the access rules defined by an “administrator” (col. 4 line 1 to col. 5 line 15, col. 6 lines 5-43, col. 7 line 45 to col. 8 line 33, col. 9 lines 10-68);

(c/d) granting a user, such as a primary care provider, access to certain defined (reads on “predetermined”) data objects based on a set of access rights, wherein an example of Gupta’s method is as follows (see Figure 1, col. 3 lines 35-59): “A subject, Dr. Smith has a relationship with an object entitled John Doe’s patient folder. By virtue of this relationship, Dr. Smith has a potential to access to the patient folder of John Doe. However, Dr. Smith does not have indiscriminate access to all parts of the folder. The relationship between the subject and the object specifies the role of the subject for the

object. The role in this case is that of a Primary Care Provider (PCP). The patient folder is marked with security classification labels that indicate the type of information from a security perspective and its sensitivity. Every role is defined with access rights that preferably include security classification labels and function classifications. Thus, Dr. Smith has read-only access to the part of the folder that is marked as PatientBio, except the part that is marked PatientBioSensitive. He also has read-only access to the part of the folder that is marked as PatientFinancial, except the part that is marked PatientFinancialSensitive. He has full access to the parts of the folder marked PatientClinical, including the parts that are marked PatientClinicalSensitive.” (Figure 1 and 4-5, col. 7 line 45 to col. 8 line 32, col. 11 lines 60-68) (It is noted that Gupta’s “role defined with access rights that preferably include security classification labels and function classifications” are considered to be a form of “first access parameter is present”);

(e) granting access to certain data objects based on a set of access rights, wherein granting access as discussed above in sections c/d includes granting access to subjects based on specific roles, wherein the subjects include the CFO having access to PatientFinancial and PatientFinancial Sensitive information and the Consultant having access to PatientClinical and PatientBio information, wherein the subjects CFO and Consultant gain access to different types of data objects, and wherein the PCP discussed above in section c/d has access to PatientBio, PatientFinancial, and PatientClinicalSensitive (Figure 1 and 4-5, col. 7 line 45 to col. 8 line 32, col. 11 lines 60-68) (It is noted that the CFO, Consultant, and PCP have access to different data

objects within Gupta's system based on a role defined with access rights that preferably include security classification labels and function classifications); and

(f) denying a user access to a data object if no relationship exists between the user and the data object (Figures 4-5, col. 7 line 45 to col. 8 line 63, col. 11 lines 35-68, col. 12 lines 25-30) (It is noted that in Figure 5, if no relationship exists between the user and the user's role and the data object, the user is denied access to the data object).

Gupta is entirely silent as to the person who determines access rules. Gupta discloses only that an administrator defines the rules (col. 4 line 1 to col. 5 line 15, col. 6 lines 5-43, col. 7 line 45 to col. 8 line 33, col. 9 lines 10-68). Wilkins includes a patient owned and controlled electronic medical record, wherein the patient determines who has access the electronic medical record (Abstract; col. 2 lines 9-33, col. 5 line 65 to col. 6 line 58). At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include Wilkins's feature of allowing a patient to determine access within Gupta's method with the motivation of protecting the privacy of patient information (Wilkins; col. 1 lines 65-67), providing a patient reasonable quick and easy access to patient information (Wilkins; col. 2 lines 9-15), and providing a patient access to review insurance information exchanged between a health care provider and insurer (Wilkins; col. 2 lines 25-33).

Gupta fails to expressly disclose "a first predetermined group of the component fields relating to a first medical condition of the patient" and "a second predetermined group of the component fields relating to a second medical condition of the patient." Schoenberg discloses selecting subsets of a patient information, wherein when the job

function is "doctor", the subsets include patient history, physical examination data, current drug data, problem data, orders, progress notes, and summary reports, and wherein when the job function is "nurse", the subsets include problem data, care plan, orders, and critical pathways. The Examiner respectfully submits that the "doctor" subsets of data and "nurse" subsets of data are considered to be a form of "a first medical condition" and "second medical condition". At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Schoenberg within the method taught collectively by Gupta and Wilkins with the motivation of precisely controlling access to a patient's information (Gupta; col. 1 lines 19-25).

(B) As per claim 23, Gupta discloses using roles of users to provide access (see the discussion in section 3A above). As per the recitation of "a login identifier associated with the person", Gupta is entirely silent as to this element. However, Schoenberg includes invoking a security program which limits access to a user unless a valid job function related code and/or PIN is entered (col. 9 lines 10-21). At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Schoenberg within the method taught collectively by Gupta and Wilkins with the motivation of precisely controlling access to a patient's information (Gupta; col. 1 lines 19-25).

(C) As per claim 27, Gupta discloses defining a role for a patient, wherein the role defines how the patient may access or manipulate its own information, wherein for example, the patient may have read-only access to his entire folder, but can modify only his bio-data information (col. 8 lines 25-32) (reads on "personal relation"). Gupta further discloses accessing information such as only PatientClinical and PatientBio information which is part of the entire patient record (See Figure 4-5, col. 3 line 3 to col. 4 line 68, col. 7 line 45 to col. 8 line 68).

(D) As per claim 28, Gupta discloses security classifications for an instance or an attribute value, wherein the security classification for a patient diagnostic instance may be derived from the sensitivity level of the problem diagnosed thus allowing an extra level of security such as super sensitive for patients diagnosed with certain types of diseases, such as HIV (reads on "bad health of the patient") and wherein the security classification may be VIP, thus providing an added security level for VIP patients (reads on "good health of the patient" (col. 7 lines 30-45). The remainder of claim 28 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given above in claim 21, and incorporated herein.

(E) As per claim 30, Gupta discloses access rights including defining function classifications that are performed on a data object, wherein function classifications (reads on "permitted transactions") include ReadOnly access (reads on "display"), FULL access, and ReadWrite access (reads on "modify" and "create") to be performed on a

data object (Figures 4-5, col. 7 line 45 to col. 8 line 62), wherein a subject is allowed to perform a function on a data object based on the function classification. As per the recitation of "unpermitted transactions", it is respectfully submitted that if a subject of Gupta's method is not given ReadWrite Access, but only given ReadOnly Access, then writing to a specific data object would be a form of an "unpermitted transaction".

(F) As per claim 31, Gupta discloses using a database management system to secure access to data objects (col. 8 lines 65-68), wherein the data objects within the database are arranged according to the subjects of patient bio-data, insurance, financial, problems, encounters, and treatment records (reads on "types of data"), wherein a physician is able to access the objects based on access rights relating to the subjects (reads on "selectable parameters") (Figures 4-5, col. 3 line 35 to col. 5 line 67).

(G) As per claim 32, Gupta discloses as discussed above in section 3A and as displayed in Figures 4-5, a patient primary care provider accessing PatientClinicalSensitive, PatientFinancial, and PatientBio information, and a nurse accessing PatientClinical and PatientBio information (see Figures 4-5).

(H) Claim 38 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given for claim 21, and incorporated herein.

(I) As per claims 39 and 40, Gupta discloses in Figure 5 accessing data objects of PatientFinancial information and PatientFinancialSensitive about a patient (reads on “non-medical information” and “financial information”), wherein the user accessing this information is the CFO, medical director, or head of a department (reads on “individuals including billing or accounting personnel”) (Figure 5, col. 7 line 45 to col. 8 line 65).

(J) As per claim 41, Gupta discloses a nurse accessing PatientClinicalSensitive and PatientBio information, wherein the CFO role is not able to access the data objects containing this information accessed by the nurse (Figure 4-5, col. 7 line 45 to col. 8 line 65).

(K) As per claim 42, Gupta discloses in Figure 5 accessing data objects of PatientFinancial information and PatientFinancialSensitive about a patient (Figure 5, col. 7 line 45 to col. 8 line 65). However, Gupta fails to expressly disclose a first set of component fields satisfying a first criterion about monetary amounts owed by the patient and a second set of component fields satisfying a second criterion about monetary amounts owed by the patient. Schoenberg discloses displaying a subset of data for an insurance coordinator, the subsets include patient cost data, risk factor data, and claim data (reads on “first set”), and displaying a subset of data for the finance department including patient cost data, procedure cost data, and staff cost data (col. 8 line 7 to col. 9 line 20) (reads on “second set”), wherein a security program limits access to a user unless a valid job function related code and/or PIN is entered (reads on “a first and

second criterion"). It is noted that Schoenberg's disclosure of a security program based on entering a job function and PIN to access financial information is considered to be a form of "satisfying a first/second criterion about monetary amounts owed by the patient").

(L) Claim 43 repeats the same limitations as claims 27 and 40-41, and is therefore rejected for the same reasons given for those claims, and incorporated herein.

(M) Claim 44 repeats the same limitations as claims 40-43, and is therefore rejected for the same reasons given for those claims, and incorporated herein.

4. Claims 33-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. (6,024,699) for substantially the same reasons given in the previous Office Action (paper number 5). Further reasons appear below.

(A) As per claim 33-34, Surwit discloses a method for a medical data processing system (col. 1 lines 5-11) comprising:

(a) providing a server connected to one or devices or monitors, wherein the server includes database for storing and manipulating patient data (col. 9 lines 24-48);
(b) identifying emergency medical conditions within the server based on physiological data, behavioral data, and patient name data, collected (Figure 8, col. 12 line 15 to col. 16 line 57 and col. 17 lines 1-15);

- (c) analyzing data transmitted from a patient monitoring system substantially simultaneously with the transmission thereof to the server to identify emergency medical conditions requiring immediate medical attention (col. 23 lines 20-25); and
- (d) automatically communicating treatment information to the respective patient monitoring system (reads on "non healthcare provider") for the patient for an identified emergency medical condition (col. 23 lines 25-30).

It is respectfully submitted that Surwit's "identifying emergency medical conditions within the server based on physiological or behavioral data collected" (col. 12 line 15 to col. 16 line 57 and col. 17 lines 1-15) is considered to be a form of a threshold event as the patient's medical condition is above a certain level. It would be an obvious modification to include using a specific threshold event within the method of Surwit with the motivation of immediately notifying medical personnel of an emergency (Surwit; col. 2 lines 55-63).

As per the recitation of "the threshold event defined by the patient", it is respectfully submitted that typically in patient monitoring, a patient would agree with a medical professional as to what events or conditions of a patient are to be monitored, and therefore it would have been an obvious modification to the method of Surwit to include allowing a patient to define a threshold event with the motivation of facilitating patient behavior modification (Surwit; col. 4 lines 28-38).

As per the recitation of to a non health care provider "selected by the patient", it is respectfully submitted that Surwit's system provides for automatic communication of information, and typically in health care management, a patient must provide approval

for communicating medical information to an outside approval. Therefore, it would have been an obvious modification to the method of Surwit to include a non health care provider "selected by the patient" with the motivation of ensuring the privacy of a patient's medical information is protected.

(B) As per claim 37, Surwit discloses the emergency medical condition relating to collected behavioral or physiological data, automatically communicating treatment information to the respective patient monitoring system of a child patient for an identified emergency medical condition, and communicating messages to the patient to schedule an office visit with a physician or to alter transmission schedules (col. 8 lines 18-35, col. 17 lines 1-15, col. 18 line 45 to col. 19 line 12, and col. 23 lines 25-30).

5. Claim 35-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. (6,024,699) as applied to claim 33 above, and further in view of Campbell et al. (6,208,974), for substantially the same reasons given in the previous Office Action (paper number 5). Further reasons appear below.

(A) As per claims 35-36, Surwit includes means for automatically communicating information to the respective patient monitoring system for the patient for a identified condition (col. 23 lines 25-30). However, Surwit fails to expressly disclose a threshold event relates to monetary amounts owed by the patient to a health care provider, wherein the electronic notification includes a request to make payments to the health

care provider after services are performed. Campbell discloses a billing function within software on a central computer over a computer network for managing patient visits and keeping patient records, wherein the central computer indicates when a patient's account is overdue (col. 2 lines 5-20). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the components of Campbell within the method of Surwit with the motivation of to receive appropriate compensation for services rendered by the health care provider (Campbell; col. 1 lines 19-31).

Response to Arguments

6. Applicant's arguments with respect to claims 21, 23, 24, 27, 28, and 30-44 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's arguments filed 27 June 2003 have been fully considered but they are not persuasive. Applicant's arguments will be addressed in the order in which they appear in the response filed 27 June 2003.

(A) At pages 14 and 18-19 of the 27 June 2003 response, Applicant argues that the applied references do not teach the features of claims 33-37.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 27 June 2003 amendment, have been fully addressed by the Examiner as either being fully disclosed

or obvious in view of the collective teachings of Surwit and/or Campbell, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number 5), and incorporated herein.

In addition, it appears Applicant is attacking the references individually, and therefore one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "empowers a patient to dynamically define who will receive an automatic notification based on a complex combination of physiological and non-physiological considerations that constitute a threshold event", "automatically notify a non medical care provider upon satisfaction of a complex, hybrid threshold event involving more than exclusively medical considerations and more than exclusively financial considerations")

are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches a method and system for distributing health information using privacy levels (6,463,417).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

10. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 [Official communications; including After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB

CB

August 28, 2003



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